REMARKS

Reconsideration of the present application in light of the amendments and remarks set forth here is respectfully requested.

As a preliminary matter, Applicants thank the Examiner for withdrawal of the previous rejection under 35 U.S.C. § 112, second paragraph. Applicants apologize for any inconvenience that may have been caused by the inadvertent failure to include with the response filed January 3, 2007, a "copy of the trademark search fro the U.S. Patent and Trademark Office website conducted 11-20-2006." Applicants thank the Examiner for noting this oversight. Said copy is included herewith for the record.

Claims 1, 2, 5, 7, and 8 are pending in the subject application. Claim 8 was previously withdrawn. Claim 1 has been amended herein. Support for the amendment to the claim may be found throughout the application and claims as originally filed, specifically, for example, at page 4, line 28, to page 5, line 1; page 11, line 20, to page 12, line 13; page 17, lines 20-21; and page 21, lines 9-13 and 16-23, of the instant specification. No new matter has been added to the application by way of these amendments. The amendments are not to be construed as acquiescing to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Claims 1, 2, 5, and 7 are now under consideration.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1, 2, 5, and 7 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. In particular, the Action asserts that in claim 1 "requires that the bacteria and nutrient within the composition be "mixed and incubated prior to use," and that this is "confusing." The action further asserts that "the limitation 'prior to use' is confusing." Without acquiescing to the rejection and solely to advance prosecution, claim 1 has been amended to more clearly identify characteristics of the kit to which claim 1, and thus claims 2, 5, and 7, are directed. In particular, the kit to which claim 1 is directed comprises bacteria and a nutrient

wherein the kit is formulated to be administered internally, that is, non-topically, and is designed such that the bacteria and the nutrient are mixed prior to oral administration to the subject.

Applicants thus submit that the rejection of claim 1, and thus claims 2, 5, and 7, under 35 U.S.C. § 112, second paragraph, has been overcome. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

Rejection Under 35 U.S.C. § 103(a)

Claims 1, 2, 5, and 7 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious in light of Farmer (U.S. Patent No. 6,645,506), in view of Jaffe (U.S. Pat. No. 3,853,454). In particular, the Action asserts that Farmer ('506) "teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide" and "may also comprise one or more of numerous probiotic bacteria." The Action also asserts that the composition of Farmer "may further comprise an antimicrobial agent ... and an antioxidant." The Action concedes that Farmer "does not explicitly teach a composition comprising ascorbate or ascorbic acid' but asserts that Jaffe ('454) "teaches that ascorbic acid was a well-known antioxidant at the time of the invention of Farmer." The Action alleges that "the skilled artisan would have been motivated to add ascorbic acid to the composition of Farmer because Farmer suggests including antioxidants to facilitate the growth and germination of the bacteria within the composition (column 17, lines 21-42)." Applicants traverse this ground for rejection and submit that, either alone or in combination with Jaffe, Farmer does not disclose, teach, or suggest the subject matter claimed in instant claim 1, as amended.

The Action asserts that "a person of ordinary skill in the art would have had a reasonable expectation of success in including ascorbic acid in the composition of Farmer because Farmer suggests adding 'known antioxidants.'" In particular, the Action asserts that "Farmer suggests including antioxidants to facilitate the growth and germination of the bacteria within the composition" and that this alleged teaching by Farmer would have motivated the skilled artisan "to add ascorbic acid to the composition of Farmer." Applicants disagree and respectfully submit that the Action has misrepresented the teaching of Farmer with respect to antioxidants. Applicants submit that column 17, lines 21-42, of Farmer lists in the alternative a

number of possible components that may be included in the disclosed compositions: "The formulation ... may include other probiotic agents or nutrients for promoting spore germination and/or Bacillus growth. The composition may also include known anti-microbial ... agents ... The therapeutic compositions may also include ... known antioxidants ...; buffering agents; lubricants (e.g., ... beeswax); sunscreens ...; and other cosmetic agents (e.g., coloring agents, fragrances, ...)." (emphasis added) Applicants submit that the cited paragraph from Farmer, which is the only disclosure of antioxidants in Farmer, does not disclose or suggest antioxidants to facilitate growth and germination of bacteria, but rather known antioxidants, together with sunscreens and fragrances, are included in a list apparently referring to cosmetic agents. Applicants submit that Farmer, with or without Jaffe, provides no motivation to incorporate within the composition as claimed in instant claim 1 an antioxidant, specifically ascorbic acid, or any other of the listed cosmetic agents. Applicants submit that there is particularly no motivation provided by Farmer to add any of the listed cosmetic agents, including antioxidants, to compositions formulated for oral administration, as claimed in claim 1, as amended.

The Action further asserts that, even if Farmer had not explicitly suggested including antioxidants in their composition, it would have been obvious to do so. The Action asserts, on the basis of the findings by the Court in *Dystar Textilfarben Gmbh & C. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d (Fed.Cir. 2006), that Farmer need not itself suggest or motivate one to incorporate antioxidants in the composition, but that "common knowledge and common sense" may be combined with Farmer to provide motivation in establishing a prima facie case of obviousness. The Action thus combines the alleged "expressly stated utility of the compositions of Farmer" in "the treatment of infections of the skin" with teachings of Grossman et al. (U.S. Patent No. 4,986,985) and Schrauzer (U.S. Patent No. 5,236,697), alleged to pertain to general use of antioxidants to treat skin infections or skin conditions, to conclude that "the motivation to include antioxidants in the composition of Farmer can be found ... in the common knowledge of the art and common sense of its skilled practitioners." Applicants respectfully traverse this further basis for alleging obviousness of instant claim 1 in light of Farmer.

Instant claim 1, as amended, and thus claims 2, 5, and 7 depending therefrom, is directed to a kit comprising bacteria, a nutrient, an antimicrobial agent, and ascorbic acid, formulated for oral administration to a subject. As clearly disclosed in the instant specification, the kit to which the instant claims are directed is formulated to be administered in particular to establish or reestablish the flora in the alimentary canal by stimulating growth and proliferation of probiotic or beneficial bacteria in subjects in which said flora have been depleted by certain treatments or medical conditions. Applicants submit that any disclosure in the art, including that cited in Farmer, related to topical applications of antioxidants or their use in treating infections, for example, skin infections, is not relevant to instant claim 1, as amended. Applicants, in fact, submit more broadly that any disclosure in the art pertaining to compositions formulated for topical application of bacteria, whether or not including bacterial nutrients or anti-microbial agents, for whatever purpose is not relevant to instant claim 1, and thus instant claims 2, 5, and 7 depending therefrom.

In addition to the above Remarks, Applicants provide herewith objective evidence supporting secondary considerations of non-obviousness, as noted by the Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). As discussed by the Court, secondary considerations of non-obviousness include criticality, unexpected results, commercial success, long-felt but unsolved needs, failure of others, and the skepticism of experts. *Id.* Applicants note that Affidavits or Declarations containing evidence of secondary considerations of non-obviousness, when timely presented, must be considered by the Examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103(a). MPEP §716.01(a).

Accordingly, Applicants enclose the Declaration of Pamela M. Drake, President of Flora Technologies (unsigned; signed version to follow), in addition to copies of letters signed by numerous medical practitioners, in support of the assertions as discussed herein. For example, the evidence provided in the enclosed Declaration and letters relates to both the criticality and long felt-need with respect to a safe and effective product that combines both anti-microbial and probiotic treatments in a single kit, according to the subject matter of the instant claims.

Briefly, Applicants submit that practicing primary care physicians find it difficult and impractical to prescribe probiotic treatments alongside their prescriptions for anti-microbial treatment for a number of reasons. For one, insurance companies do not typically cover the cost of separate probiotic treatments, so patients must pay for the additional treatment separately, out of their own pockets (*see e.g.,* enclosed letter from Maribeth T. Duffy, M.D.). Moreover, pharmacies rarely sell probiotic treatments, so patients must make a separate trip to specialized stores selling probiotic supplements (*see e.g., Id.*). Primary care physicians express that their patients would benefit greatly by the availability of a kit that combines anti-microbial and probiotic treatments in a single kit or prescription, and affirm that they would routinely prescribe such a kit if it were available (*see e.g., Id.*).

Embodiments of the present invention are directed in pertinent part to a kit comprising: (i) isolated or purified bacteria, (ii) a nutrient for the isolated or purified bacteria selected from the group consisting of: spirilina, chloraphyllins, fructooligosaccharides, and methylsulfonylmethane, (iii) an antimicrobial agent, and (iv) ascorbic acid, wherein said bacteria and nutrient are mixed and incubated prior to administration to the subject. Applicants submit that embodiments of the present invention satisfy the aforementioned long-felt need for a combination treatment, in part by providing a kit that combines anti-microbial and probiotic treatments in a single prescription.

Additionally, it is the experience of practicing physicians that the actual cost of treating patients increases because of anti-microbial related disruptions to the intestinal flora, which often create complications requiring continual medical intervention (*see e.g.,* enclosed Letter from Patrick Litster, MPAS, PA-C). One solution lies in re-establishing healthy flora, *e.g.,* healthy intestinal flora, which may be accomplished by administering a probiotic alongside the anti-microbial (*see e.g.,* enclosed Letter from Roy Ozanne, M.D.). Naturally, treatments relating to problems with the intestinal flora require the use of an anti-microbial/probiotic treatment that may be administered accordingly, *i.e.,* a treatment that is not exclusively topical. Thus, Applicants submit as well that there is the same long-felt need for an anti-microbial/probiotic kit that is not exclusively topical, which is satisfied by embodiments of the present invention.

Moreover, the present invention satisfies this long-felt need at a critical time, when physicians are noting an increase in cases of resistant infections and other complications following present antibiotic usage. Routine antibiotic use contributes to a significant health problem, the growth of opportunistic, anti-microbial resistant infections such as Methicillin Resistant *Staphylococcus aureus* (MRSA), *E.coli*, *Clostridium dificile* and fungal infections (*see e.g.,* enclosed Letter from Roy Ozanne, M.D.). Acute infections become chronic infections that do not necessarily respond to antibiotics (*see e.g.,* enclosed Letter from Ann Tosomeen, M.D.). The present standard of care relating to antibiotic usage does not include the concurrent use of probiotics, and physicians indicate that the medical community is missing an opportunity to forestall the significant and critical problem relating to opportunistic infections caused by the use of anti-microbials (*see e.g.,* enclosed Letter from Roy Ozanne, M.D.).

In light of the remarks and reasons as provided herein, Applicants respectfully submit that the claims are non-obvious in light of the cited references. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a).

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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WTC:DLE:jto

Enclosures:

Trademark search for "nystatin" from the U.S. Patent and Trademark Office website conducted 11-20-2006.
Declaration of Pamela Drake.

Letters from Roy Ozanne, M.D., H.M.D., Colette M. Kato, D.O., Patrician Sylwester, M.D., Karolina Wilczynaka-Oberc, M.D., Patrick Litster, M.P.A.S., PA-C, Ann Tosomeen, M.D., Maribeth T. Duffy, M.D., and Pamela J. Baxter, PA-C, R.T.R.M.

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